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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,398	10/24/2003	Lee A. Core	106586-172 US2	2513

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WILMER CUTLER PICKERING HALE AND DORR LLP
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BOSTON, MA 02109

EXAMINER

GETTMAN, CHRISTINA DANIELLE

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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05/07/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/693,398

Applicant(s)

CORE, LEE A.

Examiner

Christina D. Gettman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/24/2003, 04/12/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION***Claim Objections***

Claims 26 and 32 are objected to because of the following informalities: the Examiner believes that the Applicant meant to say that the elasticity of the outer layer is greater than the elasticity of the inner layer, as stated in the specifications. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12-16, 19-23, 32, 37, 38-39, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (U.S. Patent No. 5,318,588). Horzweski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the conduit being an introducer sheath or a catheter (obvious variations of one another), the inner layer having a slit (ref. 13, Fig. 1B) and an overlapping portion (see Fig. 1B) to help expand the inner layer, a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it, and a method of using the device (see Fig. 2A-2F).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-11, 17-18, 24-25, 33-36, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. as applied to claims 4, 16, 1, 23, 19, 32, 39 and 38. Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. The other geometric formations are obvious variation of having a slit and/or an overlapping section that would obtain the same results of expanding the inner layer of the conduit. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with a different geometric formation of the inner layer of the conduit and with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen.

Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. in view of Querns et al. (U.S. Patent No. 5,944,691). Horzewski et al. disclose an introducer sheath/catheter having two layers that are bonded to one another and the inner layer having means for allowing its diameter to expand. Horzewski et al. do not disclose a method of how the sheath/catheter is formed. Querns et al. teach the method of co-extrusion (col. 3, line 43-54) for the purpose of forming a two-layered sheath/catheter. It is also an obvious well-known variation to use a method of dipping instead of co-extrusion to form the sheath/catheter. Therefore, it would have been obvious to have made the sheath/catheter by either co-extrusion or dipping in order to form a two-layered sheath/catheter.

Conclusion

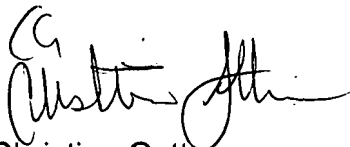
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherry (U.S. Patent No. 6,368,238), Taylor et al. (U.S. Patent No. 5,938,587), and Stone (U.S. Patent No. 6,312,443) all disclose expandable sheaths/catheters to be used for inserting a medical device into a body lumen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina D. Gettman whose telephone number is 571-272-3128. The examiner can normally be reached on Monday-Friday 7:15 am to 3:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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571-272-3128



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER